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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,724	11/07/2001	Michael N. Gould	960296.97711	7402

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EXAMINER
JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/25/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/014,724	Applicant(s) GOULD ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 12, filed 6/24/03, wherein claims 1-9 were canceled.

Note: Claims 17-33 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 6/24/03 (Paper No. 12) to the rejection of claims1-9 and 17-33 made by the Examiner under 35 USC 102, 103, and/or double patenting have been fully considered and deemed persuasive for the reasons below. Therefore, the said outstanding rejections are hereby withdrawn.

Statutory Double Patenting

The double patenting rejection is WITHDRAWN because Applicant has abandoned serial number 09/878,797.

102 Rejections

The 102 rejections over Gould et al (US Patent No. 5,587,402), Miller et al (Eiconsanoids and Other Bioactive Lipids in Cancer, Inflammation, and Radiation Injury 2, 1997, pp. 825-830), and Myers et al (WO 94/20080) are WITHDRAWN for reasons of record in Applicant's response.

103 Rejections

The 103 rejection of Myers et al in view of Gould et and Miller et al in view of Gould et al are WITHDRAWN for reasons of record in Applicant's response.

NEW GROUNDS OF REJECTION

103 Rejections

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 17, 18, 22-26, and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haridas et al (US 2003/0054052 A1).

Haridas et al disclose triterpene compositions and uses thereof (see entire document, especially, abstract). The compositions comprise typically comprise a monoterpene moiety or moieties (page 2, paragraph [0013]). The compositions may comprise other components like immunodulators (page 7, paragraph [0058]). The triterpene compositions may be administered to a subject to prevent cancer or as a therapeutic treatment after the detection of cancer (pages 26-27, bridging paragraph). Pharmaceutical compositions comprising the triterpene compounds may be powerful chemotherapeutic drugs which may be used by themselves or in combination with other forms of cancer therapy such as chemotherapy, radiation therapy, surgery, gene therapy, and immunotherapy (pages 27-28, bridging paragraph; pages 30-31, paragraphs [0393] and [0394]; page 31, paragraphs [0395] – 0398]; page 33, paragraphs [0403] – [0404]). Haridas et al disclose the use of toxins for certain applications wherein a second therapeutic agent is used in combination with the

triterpene compound. Possible agents which may be used to generated the modified composition include chemotherapeutic agents, radioisotopes, and cytotoxins. Other embodiments include agents such as cytokines (page 37, paragraphs [0439] – [0440]). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a method of sensitizing tumor/cancer cells to chemotherapy or immunodulatory agents because Haridas et al disclose the use of a monoterpene composition use in combination with a chemotherapeutic agent or immunodulatory agent and radiation useful for prophylactically preventing cancer or therapeutic use after cancer detection to inhibit the initiation and promotion of cancer, to kill cancer/malignant cells, to inhibit cell growth, to induce apoptosis, to inhibit metastasis, to decrease tumor size, or to otherwise reverse or reduce malignant phenotype tumor cells.

5. Claims 17, 18, 23-26, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakshatri et al (US 2003/0125373 A1).

Nakshatri et al disclose a therapeutic method of treating cancer comprising administering an effective amount of parthenolide (a sesquiterpene lactone) or an analog thereof to a subject (see entire document, especially, abstract; page 1, paragraph [0007]; page 2, paragraph [0023]). In addition, Nakshatri et al disclose a method of increasing the susceptibility of human cancer cells to a chemotherapeutic agent by administering parthenolide (page 1, paragraphs [0008] – [0009]). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to use a sesquiterpene, parthenolide or an analog thereof, in combination with radiation for sensitizing tumor cells to chemotherapy because Nakshatri et al disclose the use of a sesquiterpene in increasing the susceptibility of cancer cells to a chemotherapeutic agent wherein the sesquiterpene may be administered as a primary therapy, or as an adjunct therapy, either following local intervention such as surgery, radiation, or local chemotherapy, or in conjugation with at least one other chemotherapeutic agent.

6. Claims 17-22 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haridas et al (US 2003/0054052 A1) in view of Gould et al (US Patent No. 5,587,402).

Haridas et al (see discussion above) fail to disclose the use of specific monoterpenes such as perillyl alcohol, limonene, and carvone with tumors/cancers.

Gould et al disclose the regression of mammalian leukemia cell tumors wherein perillyl alcohol is administered to a subject (see entire document, especially, abstract). In addition, Gould et al disclose (1) that it is possible to test the measurement of protein isoprenylation by incubating extracts with a radioactive isoprene and visualizing the protein by fluorography (columns 2-3, bridging paragraph). (2) Various monoterpenes such as limonene, perillyl alcohol, sobrerol, myrcene, pinene, cavone, terpineol, and uroterpenol (see column 4, Table 1) were analyzed for their ability to inhibit isoprenylation in mouse embryo cells. (3) Various concentrations of perillyl alcohol was used and shown to inhibit growth of a number of human cancer cell lines (column 5,

lines 8-13). (4) The effects of dietary perillyl alcohol on tumor regression and inhibition in rats were studied (columns 5-6, lines 14-68 and 1-68, respectively). (5) In column 7, lines 35-68, in vivo experiments are conducted using perillyl alcohol in patients with leukemia. (6) In column 8, lines 33-58, experiments were conducted with perillyl alcohol and limonene. Later, IL-3 was added. It should also be noted Gould et al disclose the use of cytokines, alpha interferon or interleukin-3, in their leukemia experiments (column 7, line 56 – column 8, line 58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Haridas et al using the teachings of Gould et al and used perillyl alcohol for the tumors/cancer because Gould et al disclose some monoterpenes (e.g., limonene, myrcene, carvone, and perillyl alcohol) that are known to be useful with cancers. Furthermore, since both Haridas et al and Gould et al are directed to cancers/tumors, the references may be considered to be within the same field of endeavors. Thus, the references are combinable.

7. Claims 17, 18, 20, 21, 26, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haridas et al (US 2003/0054052 A1) in view of Myers et al (WO 94/20080).

Haridas et al (see discussion above) fail to disclose some specific monoterpenes that are useful with cancers/tumors.

Myers et al disclose the use of monoterpenes and sesquiterpenes in the treatment of cancer. The treatment involves administering an effective amount of a

selected terpene to a mammal having prostate cancer, colon cancer, astrocytoma, or sarcoma. Possible terpenes include cyclic monoterpenes (e.g., limonene), non-cyclic monoterpenes (e.g., myrcene and citral), and non-cyclic sesquiterpenes (e.g., farnesol, farnesal, farnesylic acid, and nerolidol). In addition a method of sensitizing a cancer to radiation is disclosed that involves administering an effective amount of the terpene to a mammal. Also, Myers et al disclose a method of inhibiting the growth of cancer cells wherein a terpene comes in contact with prostate, colon, osteosarcoma, or glioblastoma cells (see entire document, especially, abstract; pages 2-3, bridging paragraph; pages 6-7, bridging paragraph; pages 8-9. Compounds 1-11; page 16, 'Sensitizing a Cancer to Radiation'; pages 19-20, Table 1; Pages 20-21, Example 2; pages 21-22, Example 3; pages 22-23, Example 5; and page 25, claim 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Haridas et al using the teachings of Myers et al and use various monoterpenes such as limonene or myrcene because Myers et al disclose some monoterpenes that are known to be useful with cancers. Furthermore, since both Haridas et al and Myers et al are directed to cancers/tumors, the references may be considered to be within the same field of endeavors. Thus, the references are combinable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640.

The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

September 22, 2003